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| 10/535,447 | 10/31/2006 | Albert K. Tai | EX03-086C-US | 8814 |

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| EXAMINER | |
|---|---|
| YU, MISOOK | |

| ART UNIT | PAPER NUMBER |
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| 1642 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/535,447 | TAI ET AL. | |
| | Examiner | Art Unit | |
| | MISOOK YU | 1642 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *11 February 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) *13-15 and 20-25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☒ Claim(s) *11,12 and 16-19* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/17/06,9/18/06,9/1/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Election/Restrictions*

Applicant's election of group I, claims 1-12 and 16-19 with proliferation assay as species in the reply filed on 02/11/2009 is acknowledged. Claims 13-15 and 20-25 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 02/11/2009. Claims 1-25 are pending and claims 1-12 and 16-19 are examined on merits.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-6 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Kornblau et al., 1994, Cancer Research, vol. 54, pages 242-246 as evidenced by Li et al., IDS filed on 11/17/2006, JBC, vol. 269, pages 18616-18622.

Claims 1-6 and 8 are drawn to a method of method of identifying RB modulating agent and the assay system requires a CCT6 polypeptide or nucleic acid expressing/encoding nucleic acid, an agent, and a control.

Kornblau et al., on page 244, right column under the sub-heading **Mitogen Stimulation of RB expression in CLL** teaches a method of identifying RB modulating agent comprising a CCT6 polypeptide or nucleic acids i.e. chronic leukemic lymphocytes (CLL), and contacting the CLL with PWM and PHA, whereby a difference in RB expression is detect between the reference point (control) and PWM and PHA treated CLL. Also note Fig. 3 on page 245.

Li et al., is cited here as evidentiary reference to show that CLL taught by Kornblau meets the limitation "aCCT6 or nucleic acid" in the instant claim 1 since Li et al., on page 18620, left column under the sub-heading *Tcp20 Is a Component of TRiC* teach that human CLL inherently has Tcp20 (same as the limitation "CCT6").

As for proliferation assay, Kornblau et al., on page 242, right column, 3rd full paragraph teaches "To assess whether the level of RB was associated with changes in the proliferatative rate, we compared the lymphocyte doubling time".

As for claim 8, PWM and PHA taught by Kornblau et al., are considered nucleic acid modulator since they are mitogens and stimulate transcription of Rb.

Claims 1-5, 7, and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Li et al., IDS filed on 11/17/2006, JBC, vol. 269, pages 18616-18622.

Li et al., on page 18620, left column under the sub-heading *Tcp20 Is a Component of TRiC* teach a method of screening an antibody (AB5) binding to Tcp 20 using CLL lysate. Note Fig. 6 also. As for claim 8, phorbol ester is considered as nucleic acid modulator since Li et al. teaches phorbol ester treatment to CLL increased Tcp20 concentration.

Claims 1 and 8-10 are rejected under 35 U.S.C. 102(b) as being anticipated by US 20030109465 (filing date of 07/06/20010.

Claims 1 and 8-10 are broadly drawn to a screening method using a system comprising a CCT6 nucleic acid.

Since US 20030109465 teaches the antisense method is done in human cells, and claims 1 and 8 as currently construed says that only requirement in the assay system is a CCT6 nucleic acid, the system used in US 20030109465 (i.e. human cells) inherently has a genomic CCT6 nucleic acid.

US 20030109465 teaches following:

Detail Description Paragraph:

[0162] In one aspect of the invention, an antisense oligonucleotide effective to block the expression of TGF-.beta., preferably an uncharged PMO antisense finds utility in practicing the invention. In another aspect, the antisense oligonucleotide is a PMO directed to a region spanning the start codon of an mRNA specific to a factor involved in TGF-.beta. signal transduction, e.g., Vla-4, tissue transglutaminase, type I or type II TGF-.beta. receptor subunits, Smad 2&3, Rb-1, p21 or a p27 signaling components.

Alternatively, the splice acceptor region of an mRNA associated with TGF-.beta. expression is targeted by a PMO for use in practicing the invention.

***Conclusion***

Claims 11, 12, and 16-19 are objected since they depend on the rejected base claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU whose telephone number is 571-272-0839. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MISOOK YU

Primary Examiner
Art Unit 1642

/MISOOK YU/
Primary Examiner, Art Unit 1642